



NDA 214787/S-05

**SUPPLEMENT APPROVAL/
FULFILLMENT OF POSTMARKETING COMMITMENT**

Gilead Sciences, Inc.
Attention: Anna Marie Tuazon, PhD
Senior Manager, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Dr. Tuazon:

Please refer to your supplemental new drug application (sNDA) dated and received January 21, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Veklury (remdesivir) injection, 5 mg/ml, Veklury (remdesivir) for injection, 100 mg/vial.

This Prior Approval supplemental new drug application provides for the following:

- To update WARNINGS AND PRECAUTIONS, 5.3 Risk of Reduced Antiviral Activity When Coadministered with Chloroquine Phosphate or Hydroxychloroquine Sulfate; DRUG INTERACTIONS; and CLINICAL PHARMACOLOGY, 12.4 Microbiology with information regarding the potential antagonistic effect of chloroquine/hydroxychloroquine on VEKLURY

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Prescribing Information, and Patient Package Insert), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated January 21, 2021, containing the final report for the following postmarketing commitment listed in the October 22, 2020 approval letter.

- 3919-10 Submit a complete study report for the assessment of the antagonistic effect of chloroquine/hydroxychloroquine on the antiviral activity of remdesivir against SARS-CoV-2 in human lung cells.

We have reviewed your submission and conclude that the above commitment was fulfilled.

We remind you that there are postmarketing requirements and postmarketing commitments listed in the October 22, 2020 approval letter that are still open.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

If you have any questions, call Christine Kim, Regulatory Project Manager, at (301) 796-5964 or at the mainline at (301) 796-1500.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director
Division of Antivirals
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

POONAM MISHRA
02/22/2021 09:41:43 AM
on behalf of Division Director